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SECTION 7: 510(k) SUMMARY

Letterhead

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.
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Device Names:

Common Name: Endosseous Dental Implant for Single Stage Surgical Placement
Trade Names: See appended list (page 4)
Classification Name: Endosseous Implant (all designs)

Predicate Device:

Substantial equivalence is claimed to

Steri-Oss' Oss' "Titanium Alloy Screw Series Implant For Single Stage Surgical Placement ("SSP")", an uncoated 3.8-mm diameter threaded titanium alloy implant (510(k) number K944158, Steri-Oss catalog numbers 2208, 2210, 2212, 2214, 2216, and 2218).

Device Description:

1) How The Device Functions:

Steri-Oss Single Stage Surgical Placement dental implants are designed to serve as supports for prosthetic devices intended to restore a patient's chewing function.

SECTION 7: 510(k) SUMMARY (continued)

Device Description (continued):

2) Scientific Principles:

Natural teeth are anatomically composed of a root - the subgingival portion of the tooth - and a crown - that part of the tooth above the gum. Dental implants are intended to mimic the root portion of this structure to aid in restoration of chewing function in patients who have lost natural dentition through disease, trauma or other cause. Implants integrate into the jaw bone. By providing a stable foundation analogous to the root portion of a natural tooth, and in combination with an abutment structure (i.e., a foundation for an artificial crown), dental implants provide a platform upon which the dentist can build an artificial crown or bridge, thereby restoring the patient's ability to chew.

3) Physical Characteristics

The Steri-Oss Single Stage Surgical Placement implants are slightly tapered and vary in diameter from 3.25 millimeters to 5.0 millimeters (neck dimension) depending upon the specific implant design, and vary from 8 millimeters to 18 millimeters in length. They may have no coating or a coating consisting of titanium alloy or hydroxyapatite. Titanium or hydroxyapatite coatings are applied as a plasma spray. The implants are available in cylindrical or threaded configurations and have either a flat top or a hex lock configuration at the apical surface.

Intended Use:

Steri-Oss Single Stage Surgical Placement implants are intended to serve as support for prosthetic devices to restore patient chewing function and are surgically placed using the single stage surgical placement method.

Comparison to the Predicate Device(s):

Steri-Oss implants indicated for single stage surgical placement are identical in all aspects to corresponding implants cleared for marketing for placement using the two stage surgical placement method, including the materials from which they are fabricated, the fabrication methods, the physical dimensions and geometry, the method of sterilization, the type of packaging, and all other respects.

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The following table provides a comparison of the technological characteristics of the Steri-Oss implant and the predicate device

Product Comparison

<u>Characteristic</u>	<u>Predicate Device</u>	<u>Submission Device</u>
Body Material	Titanium alloy	Same
Coating Materials	None, or HA or TPS (depending upon configuration)	Same
Design	Threaded or cylindrical	Same
Superior surface	Flat or Hex Lock	Same
Length (mm)	8, 10, 12, 14, 16, 18 mm	Same
Diameter (mm)	3.25, 3.8, 4.1/4.5, 5.0/4.5 mm	Same
Packaging	Double vial	Same
Sterility	Sterile	Same

SECTION 7: 510(k) SUMMARY (continued)

Trade Names:

- 1) Flat-top, threaded, HA-coated, 3.8-mm diameter SSP
- 2) Flat-top, cylinder, HA-coated, 3.25-mm diameter SSP
- 3) Flat-top, cylinder, HA-coated, 3.8-mm diameter SSP
- 4) Flat-top, cylinder, TPS-coated, 3.25-mm diameter SSP
- 5) Flat-top, cylinder, TPS-coated, 3.8-mm diameter SSP
- 6) Hex-lock, threaded, uncoated, 3.25-mm diameter SSP
- 7) Hex-lock, threaded, uncoated, 3.8-mm diameter SSP
- 8) Hex-lock, threaded, uncoated, 4.1-mm neck / 4.5-mm body diameter SSP
- 9) Hex-lock, threaded, uncoated, 5.0-mm neck / 4.5-mm body diameter SSP
- 10) Hex-lock, threaded, HA-coated, 3.25-mm diameter SSP
- 11) Hex-lock, threaded, HA-coated, 3.8-mm diameter SSP
- 12) Hex-lock, threaded, HA-coated, 4.1-mm neck / 4.5-mm body diameter SSP
- 13) Hex-lock, threaded, HA-coated, 5.0-mm neck / 4.5-mm body diameter SSP
- 14) Hex-lock, threaded, TPS coated, 3.25-mm diameter SSP
- 15) Hex-lock, threaded, TPS coated, 3.8-mm diameter SSP
- 16) Hex-lock, threaded, TPS coated, 5.0-mm neck/4.5-mm body diameter SSP
- 17) Hex-lock, cylinder, HA-coated, 3.25-mm diameter SSP
- 18) Hex-lock, cylinder, HA-coated, 3.8-mm diameter SSP
- 19) Hex-lock, cylinder, TPS coated, 3.25-mm diameter SSP
- 20) Hex-lock, cylinder, TPS coated, 3.8-mm diameter SSP